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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/700,491	11/05/2003	Ali Amara	03495.0300	6283

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EXAMINER	
CHEN, STACY BROWN	
ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 08/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/700,491	AMARA ET AL.	
	Examiner	Art Unit	
	Stacy B Chen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 November 2003*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-71* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-71* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. All further correspondence for this application should be directed to Art Unit 1648. Claims 1-71 are pending and subject to the following Restriction Requirement.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3, 9-14, 23-30, 38, 39 and 41, drawn to a method of preventing or treating a disease using a DC-SIGN modulator/blocker that is a derivative of an effector molecule, classified in class 435, subclass 7.2.

- Further restriction is required from claims 38-39. Applicant must elect one of human immunodeficiency virus (HIV) or simian immunodeficiency virus (SIV). If HIV is elected, claims 1-3, 9-14, 23-30, 38, 39 and 41 will be examined. If SIV is elected, claims 1-3, 9-14, 23-30, 38 and 39 will be examined.

II. Claims 1, 2, 4-6, 9-20, 23-30, 32-37 and 38-41, drawn to a method of preventing or treating a disease using a DC-SIGN modulator/blocker that is an antibody, classified in class 435, subclass 7.1.

- Further restriction is required from claims 38-39. Applicant must elect one of human immunodeficiency virus (HIV) or simian immunodeficiency virus (SIV). If HIV is elected, claims 1, 2, 4-6, 9-20, 23-30 and 32-41 will be examined. If SIV is elected, claims 1, 2, 4-6, 9-20, 23-30 and 32-40 will be examined.

III. Claims 1, 2, 7-14, 21-22 and 23-30, drawn to a method of preventing or treating a disease using a DC-SIGN modulator/blocker that is a mannosylated molecule, classified in class 435, subclass 7.2.

IV. Claims 1, 2, 9-14 and 23-31, drawn to a method of preventing or treating a disease using a DC-SIGN modulator/blocker that is a recombinantly produced protein, classified in class 435, subclass 69.1.

V. Claims 42-45, drawn to a method of preventing or treating inflammation using a DC-SIGN modulator/blocker, classified in class 435, subclass 7.2.

VI. Claims 46-49, 62 and 71, drawn to a DC-SIGN modulator/blocker that is a Dengue virus E glycoprotein, classified in class 424, subclass 218.1.

VII. Claims 46-48, 50-55 and 71, drawn to a DC-SIGN modulator/blocker that is an antibody, classified in class 424, subclass 147.1.

VIII. Claims 56-61, drawn to a method of identifying a DC-SIGN modulator/blocker, classified in class 435, subclass 4.

IX. Claims 63-70, drawn to a method of targeting a subject molecule to a cell expressing a DC-SIGN receptor, classified in class 435, subclass 4.

The inventions are distinct, each from the other because of the following reasons:

a) Within Groups I and II are distinct methods of prevention and treatment. HIV and SIV are distinct viruses that require separate searches. While they are both immunodeficiency viruses, the treatment and prevention of HIV and SIV are divergent.

b) Groups I-V, VIII and IX are all drawn to distinct methods of prevention and treatment. Group I is drawn to methods of preventing or treating HIV and SIV with a derivative of an effector molecule. Groups II-IV are drawn to methods of preventing or

treating disease using an antibody, a mannosylated molecule, or a recombinant protein. Group III uses antibodies, Group IV uses mannosylated molecules, and Group V uses recombinant proteins. These reagents do not share function, modes of operation or effect. These methods are not disclosed as capable of use together. Group V is drawn to a method of preventing or treating inflammation. Methods of treating HIV/SIV with an effector molecule use different reagents than methods that use antibodies, mannosylated molecules or recombinant proteins. Methods of treating HIV/SIV or other diseases accomplish different functions than a method of treating inflammation. Group IX is drawn to a method of identifying a product. Group X is drawn to a method of targeting molecules to cells expressing a receptor. These methods use different reagents and methodology. They have different modes of operation, function and effect. The methods are not disclosed as capable of use together.

c) Inventions (I, V, IX) and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the derivative of an effector molecule, such as Dengue virus glycoprotein E, can be used in an immunoassay for detecting antibodies.

d) Inventions (II, V, IX) and VII are related as product and process of use. The product, an antibody, can be used in a method of purifying cells that express the DC-SIGN receptor.

e) Inventions (I, III, IV) and VII are unrelated. The product of Group VII, an antibody, is not required to practice the methods of Groups I, III and IV.

f) Inventions (II-IV) and VI are unrelated. The product of Group VI, the derivative of an effector molecule, such as Dengue virus glycoprotein E, is not required to practice the methods of Groups II-IV.

g) Inventions VI and VII are unrelated. These products, the derivative of an effector molecule, such as Dengue virus glycoprotein E, and an antibody are not structurally or functionally related. These products are not disclosed as capable of use together.

h) Inventions (VI, VII) and VIII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the products can be isolated from patient samples.

i) Inventions (VI, VII) and IX are related as product and process of use. The product, derivative of an effector molecule, such as Dengue virus glycoprotein E, can be used to purify antibodies or proteins.

3. Because these inventions are distinct for the reasons given above and the literature search required for one Group is either not required or not co-extensive for any other Group, and therefore burdensome, restriction for examination purposes as indicated is proper. Applicant is reminded that upon the cancellation of claims to a non-elected

invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

4. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In*

re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996).

Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:30-4:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James C Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JEFFREY STUCKER
PRIMARY EXAMINER

SBC
Stacy B. Chen
August 12, 2004